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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,817	11/20/2003	Xi Chu		9715

7590 10/23/2006

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Mounds View, MN 55112

EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,817

Applicant(s)

CHU, XI

Examiner

DAVID J. ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-40, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-40, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The Request for Continued Examination and the accompanied amendment filed July 12, 2006 have been entered. Claims 1-28 and 41-49 remain withdrawn from consideration for being directed to a non-elected invention. Claim 51 has been newly added. Claims 1-51 are currently pending, of which claims 29-40,50 and 51 are being considered for further examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-34, 37-40,50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpentier et al. (USPN 6,039,759, as cited in last office action) further in view of either of Hanson et al [4276658] or Bokros [4178639].

Carpentier et al. discloses a trileaflet prosthetic valve with all the elements of claim 29. See Figs. 21-23 and column 13, lines 7-58 for a trileaflet prosthetic valve (510) comprising an annular valve body (512) having an inner surface and being disposed around a central axis. Three substantially identical leaflets (526, 527, 528) are mounted in the annular valve body (512) and are configured to translate between a closed position impeding blood flow through the valve and an open position allowing

Art Unit: 3738

blood flow therethrough. The annular body (512) has three pairs of symmetrically placed hinges (522, 524) spaced around on one side (the inside) of the annular body (512) for pivotally supporting the leaflets (526, 527, 528). Each hinge (522, 524), due to its shape, has a plane of symmetry containing the central axis and an opening in the form of a recess. Each of the leaflets have opposed ears (530, 532) for engaging the hinges (522, 524) and a flat edge adjacent each of the ears for engaging a surface segment. While Carpentier et al discloses the hinges to be formed in the valve body, each of Bokros and Hanson et al illustrate and teach forming the hinges on a hinge structure extended from the rim of the annular body. To move the hinge member to an extension member on the rim of Carpentier et al to avoid potential blood stagnation which could lead to clotting of the blood, would have been obvious from the teachings of either of Hanson or Bokros.

Claims 30 and 33, see Figs. 21 and 23 for each of the leaflets (526, 527, 528) further comprising a central surface having a curved outer edge (538) for engaging the inner surface of said annular body (512), an obliquely angled inner edge (536) for engaging adjacent leaflets, and two flat segments adjacent to each ear (530, 532) to guide the motion of the leaflet.

Claim 31, see Figs. 12-14. The shape of the hinge (522, 524) includes surfaces that provide as stop means for arresting movement of the leaflets.

Claim 32, see Fig. 21 for at least three supports (514') for guiding the leaflets (526, 527, 528), each of the supports comprising two flat planes (514") on the inner surface of the support.

Claim 34, see column 6, lines 64-65 for the valve body being formed from pyrolytic carbon and the leaflet substrates being formed from metal (titanium).

Claim 37 recites only an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Because the trileaflet prosthetic valve of Carpentier et al. is a prosthetic heart valve, it is capable of being implanted into a system of heart valves.

Claim 38, see Figs. 12-14 for the internal opening shape of the hinges being butterfly, or column 13, line 21 for the opening of the hinges (522, 524) being wing-shaped (triangular).

Claim 39, see Figs. 12-14 for the bottom of the hinges being a spherical depression, as best understood by the examiner.

Claim 40, see column 13, line 21; because the hinges (522, 524) are wing-shaped, the bottoms of the hinges will be half-open.

Claim 50 does not necessarily further limit the invention. The claim is dependent on claim 34, which has a listing of materials from which the valve body and the leaflets can be made. In an embodiment wherein the valve body is made from pyrolytic carbon and the leaflets are made from metal, such as in the invention disclosed by Carpentier

et al., further limiting the carbon composite material does nothing to limit the embodiment at issue. The examiner suggests amending claim 50 to first limit the material to a carbon composite, and then further limit the carbon composite as set forth in the claim.

Claims 35,36 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpentier et al in view of either of Hanson et al [4276658] or Bokros [4178639] as applied to claim 29 above, and further in view of Bokros et al (3685059).


While it is not clear if the prior arts to Hanson et al, Bokros or Carpentier et al utilizes nano sized particles in engineering the pyrolytic carbon that forms the basic valve, Bokros, et al '059 teaches that nano sized particles are used in the fabrication of the valve and the coating. If not inherent in Carpentier et al, the use or to use nano sized particles in the fabrication of the matrix or as a coating for the valve body would have been obvious to one with ordinary skill in the art from the teachings of Bokros'059.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
10/12/2006